

## **REMARKS**

Reconsideration and withdrawal of the rejections of the application respectfully requested in view of the remarks herewith, which place the application in condition for allowance.

### **I. Status of Claims and Formal Matters**

The specification has been amended to correct the figure legends, delete the recitation of reference character 922 and correct an obvious error that inadvertently recited FIG. 15 instead of FIG. 16. No new matter has been added.

Claims 1-22 were pending in the present application. Claims 1-8 and 16-22 are withdrawn from consideration as allegedly being directed to non-elected subject matter. Claims 9 and 10 are amended to add the recitation of entry port chamber. Support is found, for example, in ¶ 182 of the specification as published. Claim 9 has also been amended to correct an obvious error to recite third instead of second microchannel. Support is found, for example, in ¶ 190 of the specification as published. Claim 9 has also been amended to recite analyte separation chamber as suggested by the Office Action.

The Examiner is thanked for indicating that claims 9-15 are free of the prior art.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited herein, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. The Earliest Effective Filing Date is May 22, 1998**

The Office Action alleges that the disclosures of the prior-filed applications fail to provide adequate support or enablement provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of the application. Applicants respectfully disagree and maintain that they are entitled to the priority date of May 23, 1997 and an earliest effective filing date of May 22, 1998.

### **III. The Information Disclosure Statement Complies with 37 C.F.R. § 1.98(a)(2)**

The information disclosure statement filed June 25, 2004 allegedly fails to comply with 37 C.F.R. § 1.98(a)(2). In response, a supplemental information disclosure statement is filed concurrently herewith to indicate that in accordance with C.F.R. § 1.98(d), no copy of those

documents previously submitted to or cited by the U.S. Patent and Trademark Office in predecessor application U.S. Patent Application No. 09/315,114 filed May 19, 1999, of which this application is a divisional, is submitted herewith.

#### IV. The Objections to the Drawings are Overcome

The drawings are objected to under 37 C.F.R. § 1.83(a) for allegedly not showing every feature of the invention specified in the claims. Applicants respectfully disagree and traverse the objection.

The elements of the claims depicted, for example, in FIGS. 11 and 13. For illustrative purposes, a marked-up copy of FIG. 11A is presented here:

example, with reference character 915, the second microchannel is illustrated, for example, with reference character 918, the secondary metering chamber is illustrated, for example, with reference character 919.

A first overflow portion is depicted as [A], a first metering portion is depicted as [B], a second overflow portion is depicted as [C], the first metering portion is depicted as [B], a septum is depicted as [S] and a fluid connection is depicted as [D] in the marked up FIG. 11A shown above.

The third microchannel is illustrated, for example, with reference character 941, the read chamber is illustrated, for example, with reference character 942, the secondary metering chamber is illustrated, for example, with reference character 915, the fourth microchannel is illustrated, for example, with reference character 921, the analyte separation assay chamber is illustrated, for example, with reference character 922, the analyte separation chamber is illustrated, for example, with reference character 922, the fifth microchannel is illustrated, for example, with reference character 928, the separation matrix buffer reservoir is illustrated, for example, with reference character 929, the sixth microchannel is illustrated, for example, with reference character 932, the read window manifold is illustrated, for example, with reference character 934.

A series of chambers are depicted as [V,W,X,Y,Z] in the marked up FIG. 11A shown above.

The elements of the microsystem platform of claim 10 are also illustrated in the figures. The metering capillary is illustrated, for example, with reference character 902, the overflow capillary is illustrated, for example, with reference character 903, the mixing chamber is illustrated, for example, with reference character 915, the overflow chamber is illustrated, for example, with reference character 905, the entry port chamber is illustrated, for example, with reference character 901, the capillary junction is illustrated, for example, with reference character 912, the mixing chamber is illustrated, for example, with reference character 915, the entry port chamber is illustrated, for example, with reference character 901 and the assay chamber is illustrated, for example, with reference character 922.

The sacrificial valves of claims 11-13 are illustrated, for example, with reference characters 911, 921 and 936. The third, fourth, fifth or sixth microchannels of claim 11 are illustrated, for example, with reference characters 941, 921, 928 and 932, respectively.

Accordingly, Applicants respectfully submit that the essential elements of the claims are indeed illustrated in the drawings.

The drawings are objected to under 37 C.F.R. § 1.84(p)(4) for not including a reference to 950 on page 53 of the specification. In response, the recitation of “950” has been deleted from the specification, thereby obviating the objection.

The drawings are objected to under 37 C.F.R. § 1.83(a) because FIG. 15 fails to show the details as described on the specification. In response, the specification has been amended to recite FIG. 16 as the recitation of FIG. 15 was an inadvertent typographical error.

Reconsideration and withdrawal of the objections to the drawings are respectfully requested.

**V. The Objections to the Specification are Overcome**

The specification is objected to for allegedly failing to provide proper antecedent basis for the claimed subject matter. Applicants respectfully disagree and traverse the objection. As indicated above, the claims are supported in the specification and drawings as originally filed.

Applicants are confused as the claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification. In re Benno, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Clarification is respectfully requested.

The disclosure was objected to because the description of the drawings does not address each figure. In response, the specification was amended to address the informalities.

Reconsideration and withdrawal of the objections to the specification are respectfully requested.

**VI. The Rejections under 35 U.S.C. § 112, Second Paragraph, are Overcome**

Claims 9-15 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree and traverse the rejection.

The recitations of “capillary microchannel”, “capillary” and “microchannel” are allegedly indefinite. In claim 9, there is no recitation of a “capillary”. The recitations of “capillary” in dependent claim 10 are of a “metering capillary” and an “overflow capillary” which are exemplified in the specification as originally filed (see, e.g., ¶¶ 47, 80, 81, 84, 85, 89-93, 99, 100, 104-106, 111, 112, 114-116, 119, 120, 123-125, 128, 129, 132, 136, 137, 143, 156, 157, 165,

171, 178, 182, 190, 249, 250, 253, 255, 256, 260 and 291 for recitations of metering capillary and ¶¶ 80-82, 84, 89-91, 99, 111, 119, 128, 136, 156, 170, 182, 249-251, 253-255 and 260 for recitations of overflow capillary). Accordingly, it is not relevant how “capillary microchannel differs from “capillary” as “capillary” is not recited alone but rather as “metering capillary” or “overflow capillary”.

The Office Action alleges there is no clear definition of the dimensions that distinguish a microchannel from a channel. The Examiner is respectfully directed to ¶ 77 of the specification as originally filed, in particular, the passage reproduced below.

Microchannel sizes are optimally determined by specific applications and by the amount of delivery rates required for each particular embodiment of the platforms and methods of the invention. Microchannel sizes can range from 0.02 mm to a value close to the thickness of the platform. Microchannel shapes can be trapezoid, circular or other geometric shapes as required. Microchannels preferably are embedded in a platform having a thickness of about 0.1 to 100 mm, wherein the cross-sectional dimension of the microchannels across the thickness dimension of the platform is less than 500  $\mu\text{m}$ -800  $\mu\text{m}$  and from 1 to 90 percent of said cross-sectional dimension of the platform.

One of skill in the art would gauge the metes and bounds of a microchannel based upon the teachings of the specification.

The phrase “just short” in claim 9 is allegedly confusion and indefinite. The recitation of “just short” is used throughout the specification as published (see, e.g., ¶¶ 158, 172, 184, 199, 262 and 275). As an example, the Examiner is respectfully directed to ¶ 184 of the specification as published, in particular, the passage reproduced below.

This throwaway section is arranged proximal to the entry position of capillary 918 and is separated from a metering section by a septum that extends from the distal wall of the structure to a position just short of the proximal wall of the structure. This arrangement produces a fluid connection between the throwaway section and the metering section. The metering section has a volumetric capacity of from about 5  $\mu\text{L}$  to about 10  $\mu\text{L}$  and is fluidly connected to an overflow section having an excess volumetric capacity of from about 15  $\mu\text{L}$  to about 150  $\mu\text{L}$ . The volumetric capacity of the overflow section is sufficient to accommodate the largest blood fluid volume applied to the disk.

One of skill in the art would gauge the metes and bounds of the recitation of “just short” to product a fluid connection with varying volumetric capacities (depending on the embodiment) as illustrated in the figures.

Claim 9 allegedly lacks antecedent basis for “the separation chamber”. Claim 9 has been amended to recite “the analyte separation chamber” as suggested by the Office Action.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, are respectfully requested.